AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Klaus HEILMANN et al.
Serial No.:	10/675,310
Filing Date:	September 23, 2003
For:	FILTER DEVICE
Art Unit:	1723
Examiner:	John KIM
Confirmation No.:	5354

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Signature: _____
Thomas C. Hughes

TRANSMITTAL OF APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

S I R:

Transmitted herewith for filing in the above-identified patent application is an Appeal Brief Pursuant to 37 C.F.R. § 41.37.

The Director is hereby authorized to charge payment of the 37 C.F.R. 41.20(b)(2) Appeal Brief fee of **$ 500.00** to the deposit account of **Kenyon & Kenyon LLP**, deposit account number **11-0600**. The Director is also authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account **11-0600**. A duplicate of this paper is attached for that purpose.

Respectfully submitted,
KENYON & KENYON LLP

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Klaus HEILMANN et al.
Serial No.	:	10/675,310
Filed	:	September 29, 2003
For	:	FILTER DEVICE
Art Unit	:	1723
Examiner	:	Krishnan Menon
Confirmation No.	:	5354

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Date: Nov. 10, 2006

Signature: _____ (Reg No. 42,674)

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

SIR:

On September 11, 2006, Applicants submitted a Notice of Appeal from the last decision of the Examiner contained in the Final Office Action dated June 16, 2006 in the above-identified patent application. The Notice of Appeal was received by the United States Patent and Trademark Office on September 14, 2006.

In accordance with 37 C.F.R. § 41.37, this brief is submitted in support of the appeal of the final rejection of claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117 and 119 to 133. For at least the reasons set forth below, it is respectfully submitted that the final rejections of these claims should be reversed.

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1. REAL PARTY IN INTEREST

The real party in interest in the present appeal is Fresenius Medical Care Deutschland GMBH of Bad Homburg in the Federal Republic of Germany, which is the assignee of the entire right, title and interest in the present application.

2. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellants or the assignee, Fresenius Medical Care Deutschland GMBH, "which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal."

3. STATUS OF CLAIMS

Claims 1 to 54, 65, 66, 79, 80, 93, 106 and 118 have been cancelled.

Claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117 and 119 to 133 are pending in the present application.

Claims 127 to 133 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 to 15 of U.S. Patent No. 6,641,731 ("Heilmann `731").

Claims 55 to 64, 67, 69 to 71, 76 to 78, 81, 83 to 92, 94, 95, 97 to 99, 101, 104, 105, 107, 108, 121 and 124 were finally rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,885,089 ("Hankammer").

Claims 55 to 64, 67, 69 to 78, 81, 83 to 92, 94, 95, 97 to 105, 107, 108, 110 to 117, 119 and 121 to 126 were finally rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of U.S. Patent No. 4,201,673 ("Kanno et al.") and Hankammer.

Claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117, 119 to 127 and 131 to 133 were finally rejected under 35 U.S.C. § 103(a) as unpatentable over German Patent No. 3435883 ("Heilmann `883").

Appellant appeals from the final rejection of claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117 and 119 to 133.

A copy of the appeal claims, i.e., claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117 and 119 to 133, is attached hereto in the Claims Appendix.

4. STATUS OF AMENDMENTS

In response to the Final Office Action dated June 16, 2006, Appellants filed a Notice of Appeal, which appealed the final rejection of claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117 and 119 to 133. No Amendment After Final Office Action has been filed in response to the Final Office Action of June 16, 2006.

5. SUMMARY OF CLAIMED SUBJECT MATTER

An aspect of the present application relates to a filter device for mass exchange between two media separated by a membrane and an end cap for such a filter device. Specification, page 1, lines 2 to 4; page 2, line 30 to page 3, line 3. The end cap for the filter device includes a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap. Specification, page 8, lines 1 to 9; Figure 1. A portion of the channel adjacent to the interior chamber defines a fluid flow path in a first generally axial direction. Figures 1 and 8. The end cap further includes at least one member wherein the at least one member and the end cap are a single structural component. Specification, page 6, lines 11 to 14; Figures 8, 11 and 12. The at least one member extends away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first generally axial direction and is located within the interior chamber of the end cap. Specification, page 4, lines 27 to 31; page 10, lines 15 to 20; Figures 8, 11, 12. The at least one member defines, for a fluid exiting the channel and flowing into the interior chamber of the end cap, a fluid flow path in a second direction different from the first direction. Specification, page 4, lines 27 to 31; page 8, lines 1 to 6; page 11, lines 1 to 13; Figure 12. In accordance with an embodiment of the present application the at least one member is curved. Specification, page 10, lines 11 to 14; page 11, lines 1 to 7; Figures 11 and 12. In another embodiment the at least one member is configured to impart a circular motion to fluid exiting the channel and flowing into the interior chamber of the end cap. Specification, page 4, lines 27 to 31, page 11, lines 1 to 7; Figures 11 and 12. In yet another embodiment the end cap includes at least two members, respective portions of the members being spaced equidistantly relative to each other, the distance between the respective portions of adjacent members decreasing in the second direction of flow. Specification, page 11, lines 14 to 20; Figure12. In yet another embodiment the filter device includes a casing for housing a filter element and the end cap is attachable to the casing. Specification, page 7, line 32 to page 8, line 6; Figure 1.

Another aspect of the present application relates to a hemodialyzer device. Specification, page 1, lines 1 to 7; page 2, line 24 to page 3, line 25; Figure 1. The hemodialyzer device includes a casing forming a housing, the casing having a blood outlet channel. Specification, page 7, line 32 to page 8, line 11; Figure 1. The hemodialyzer device also includes a hollow fiber bundle stored within the casing and an end cap attachable to the casing. Id. The end cap includes a blood inlet channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap. Specification, page 8, lines 1

to 9; Figure 1. Additionally, the end cap of the hemodialyzer includes features as described above regarding the end cap for the filter device, including a plurality of curved members.

Another aspect of the present application relates to a method for filtering a fluid that includes the step of passing the fluid through a filter device. Specification, page 2, line 30 to page 6, line 28. The filter device includes features as described above.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 55 to 64, 67, 69 to 71, 76 to 78, 81, 83 to 92, 94, 95, 97 to 99, 101, 104, 105, 107, 108, 121 and 124, which stand rejected under 35 U.S.C. § 102(b) as unpatentable over Hankammer, are patentable over Hankammer.

B. Whether claims 55 to 64, 67, 69 to 78, 81, 83 to 92, 94, 95, 97 to 105, 107, 108, 110 to 117, 119 and 121 to 126, which stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Kanno et al. and Hankammer, are patentable over the combination of Kanno et al. and Hankammer.

C. Whether claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117, 119 to 127 and 131 to 133, which stand rejected under 35 U.S.C. § 103(a) as unpatentable over Heilmann `883, are patentable over Heilmann `883.

As regards the double patenting rejections, these grounds of rejection are not presented for review as Appellants are prepared to submit a Terminal Disclaimer at such time that the appealed claims are otherwise in condition for allowance. Nothing in the present Brief should be construed as acquiescence to or agreement with these double patenting rejections.

7. ARGUMENTS

A. The rejection of claims 55 to 64, 67, 69 to 71, 76 to 78, 81, 83 to 92, 94, 95, 97 to 99, 101, 104, 105, 107, 108, 121 and 124 under 35 U.S.C. §102(b) as anticipated by Hankammer should be reversed.

Claims 55 to 64, 67, 69 to 71, 76 to 78, 81, 83 to 92, 94, 95, 97 to 99, 101, 104, 105, 107, 108, 121 and 124 stand finally rejected under 35 U.S.C. §102(b) as anticipated by Hankammer. It is respectfully submitted that Hankammer does not anticipate the present claims.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d

628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). It is respectfully submitted that Hankammer does not anticipate the present claims for at least the reason that Hankammer fails to disclose, or even suggest, all of the claimed features of each claim.

Independent claims 55, 69, 83, 97, 121 and 124 recite, inter alia, the feature of a channel that provides fluid communication from an exterior of an end cap to an interior chamber of the end cap, the channel defining a fluid flow path in a generally axial direction. Hankammer fails to disclose, or even suggest, at least this feature. Instead, Hankammer describes "[a] distributor cap [that] consists essentially of the umbrella-shaped bottom section 15, the vanes 4 mounted beneath, and the hollow cone 9 acting as handle and vent." Col. 4, lines 3 to 6. As described in Hankammer, hollow cone 9 is a vent which acts as an outlet for air. Hankammer specifically states that "FIG. 2 ... shows the central venting duct 11 of the hollow cone 9," col. 4, lines 9 to 10, and most importantly, that "[v]enting duct 11 has the function of venting the sealing screen 2 and hollow cone 10," col. 4, lines 45 to 47. Furthermore, as more fully set forth below, hollow cone 9 could not function as an axial flow path because to have it do so would render the Hankammer reference senseless in view of its stated purpose—to distribute fluid evenly over sealing screen 2 through the use of vanes 4. Col. 4, lines 23 to 33. For at least these reasons, hollow cone 9 is not a channel defining a fluid flow path in a generally axial direction as recited in independent claims 55, 69, 83, 97, 121 and 124.

The Final Office Action argues that "the limitation, 'channel that defines a fluid flow path in the generally axial direction' ... is not a patentable limitation since the channel of Hankammer is *capable of* having a fluid flow in the axial direction" and "air is a fluid; air escaping the vent cap is in the axial direction." Final Office Action, page 8, emphasis added. The Final Office Action's contention of what "Hankammer is capable of" is explicitly contradicted by the language of Hankammer and the Final Office Action itself. Hankammer states that "[i]t is clearly evident from FIGS. 1 to 3 that a water jet arriving from above cannot impact directly on sealing screen 2 and the filter material beneath it, which would otherwise result in flow channels forming in the filtering material." Col. 4, lines 23 to 27. Fluid enters the device of Hankammer from the sides of the device. For instance, Hankammer states that "[t]he water arriving on umbrella-shaped bottom section 15 flows

down the sides and then penetrates into the intermediate spaces between vanes 4 under distributor cap 3 and thus reaches the screening apertures of the sealing screen 2." Col. 4, lines 29 to 33. Furthermore, the Final Office Action contradicts itself and admits that "Hankammer teaches the advantages of having the vanes to guide the water to uniformly penetrate the screen over its entire cross-section, which affords a uniform distribution of water *instead of it falling vertically through the filter*." Final Office Action, page 10, emphasis added. If vent 10 was utilized as an inlet, the water would do exactly what the Final Office Action asserts Hankammer teaches against—fall vertically through the filter. Thus, the feature of a channel that provides fluid communication *from* an exterior of an end cap *to* an interior chamber of the end cap, *the channel defining a fluid flow path in a generally axial direction* is a patentable feature that is not disclosed or suggested by Hankammer.

The Final Office Action also contends that "the argument that ... [hollow cone 9] does not function as a fluid flow path is not convincing because air is a fluid, and functional language does not make the claim patentable if the prior art is so capable." Final Office Action, page 8. Applicants respectfully disagree with this statement.

First, regardless of the Final Office Action's incorrect reasoning regarding function language, Applicants respectfully submit that a channel in an end cap that defines a fluid flow path from an exterior of the end cap to an interior chamber of the end cap in a generally axial direction is a structural feature. A channel is a physical structure and this structure, as discussed above, renders independent claims 55, 69, 83, 97, 121 and 124 patentable over Hankammer.

Moreover, the recitation in Hankammer that "a water jet arriving from above cannot impact directly on the sealing screen and filter material beneath it ..." is a structural limitation. Column 4, lines 23 to 27. This structural limitation explicitly contradicts the Final Office Action's contention that the hollow cone 9 can function as a fluid flow path. As set forth above, Hankammer clearly describes a fluid entering the device from the sides and the hollow cone as a vent for air. Column 4, lines 29 to 33 and lines 45 to 47. Thus, the feature of a channel that provides fluid communication from an exterior of an end cap to an interior chamber of the end cap, the channel defining a fluid flow path in a generally axial direction is a structural limitation that belies the description of the Hankammer device as presented in the Final Office Action.

Second, the Final Office Action's argument that "functional language does not make the claim patentable if the prior art is so capable" is unsupported. Final Office Action,

page 8. Without explanation, the Final Office Action cites a string of cases. Final Office Action, pages 9 to 11. It is unclear exactly what position the Final Office Action purports that these cases support.

The Final Office Action correctly states that "'[a] patent applicant is free to recite features of an apparatus either structurally or functionally.'" Final Office Action, page 9 citing In re Schreiber, 44 U.S.P.Q.2d 1429 (Fed. Cir. 1997). The Final Office Action goes on to state that "'where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied upon,'" Final Office Action, page 9 citing In re Swinehart, 439 F.2d 210, 212, 213 (C.C.P.A. 1971). It would appear that the Final Office Action is asserting that the feature of a channel that provides fluid communication from an exterior of an end cap to an interior chamber of the end cap, the channel defining a fluid flow path in a generally axial direction is an inherent characteristic of the Hankammer reference and that the Applicants have failed to show that Hankammer does not possess this characteristic. Applicants respectfully disagree.

For the reasons set forth above, Applicants have clearly established that Hankammer does not disclose or suggest the characteristic of a channel that provides fluid communication from an exterior of an end cap to an interior chamber of the end cap, the channel defining a fluid flow path in a generally axial direction—inherently or otherwise.

Furthermore, inherency for purposes of anticipation must be certain. In re Rijckaert, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991), emphasis added. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. In re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). For the reasons set forth above, Applicants respectfully submit that it has not been established that the characteristic of a channel that provides fluid communication from an exterior of an end cap to an interior chamber of the end cap, the channel defining a fluid flow path in a generally axial direction is an inherent characteristic of Hankammer.

For at least the foregoing reasons, Hankammer does not anticipate independent claims 55, 69, 83, 97, 121 and 124.

As for claims 56 to 64, 67, 70, 71, 76 to 78, 81, 84 to 92, 94, 95, 98 to 99, 101, 104, 105, 107 and 108, each of which ultimately depends from and include all of the limitations of a respective one of independent claims 55, 69, 83 and 97, it is respectfully submitted that Hankammer does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claims 55, 69, 83 and 97.

For at least the foregoing reasons Hankammer does not anticipate claims 55 to 64, 67, 69 to 71, 76 to 78, 81, 83 to 92, 94, 95, 97 to 99, 101, 104, 105, 107, 108, 121 and 124.

B. The rejection of claims 55 to 64, 67, 69 to 78, 81, 83 to 92, 94, 95, 97 to 105, 107, 108, 110 to 117, 119 and 121 to 126 under 35 U.S.C. §103(a) as unpatentable over Kanno et al. in combination with Hankammer should be reversed.

Claims 55 to 64, 67, 69 to 78, 81, 83 to 92, 94, 95, 97 to 105, 107, 108, 110 to 117, 119 and 121 to 126 stand finally rejected under 35 U.S.C. §103(a) as unpatentable over the combination of Kanno et al. and Hankammer. It is respectfully submitted that the combination of Kanno et al. and Hankammer does not render obvious the these claims for at least the following reasons.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As for the requirement that the reference must provide a suggestion or motivation for making the proposed modification, the rejection is plainly deficient. The Final Office Action contends that "[o]ne would use the teaching of Hankammer in the teaching of Kanno because Kanno recognizes the need for proper distribution of blood without

channeling and Hankammer teaches an improved structure for obtaining such distribution ...." Final Office Action, page 6. There is no indication whatsoever of a suggestion or motivation by Hankammer or Kanno et al. to make the proposed modifications. Merely because certain references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). As discussed in further detail below, Kanno et al. are directed to diverting the flow of dialysate by a deflection member positioned inside the casing of a dialyzer. See, e.g., Figure 3 and col. 2, lines 18 to 21. Kanno et al. do not teach obtaining a proper blood distribution by the use of an end cap as recited in the claims at issue. The portion of Kanno et al. cited in the Final Office Action as providing a suggestion to combine, col. 3 line 45 to col. 4, line 39, teaches proper blood distribution as a function of the length of the inlet port, col. 4, lines 18 to 24, or as a function of a volume ratio, col. 4, lines 25 to 33. There is no suggestion in Kanno et al. that proper blood distribution would be achieved by using a structure as disclosed in Hankammer. In fact, Hankammer is directed to a totally different invention—a cap that is used to disperse water flowing into the sides of the cap into a water filter. Moreover, the device of Kanno et al. is not suitable to permit fluid flow in the manner in which fluid flows in Hankammer, i.e., through the sides of the device. The Final Office Action fails to identify where the prior art suggests the desirability of the asserted combination.

If the desirability of the combination cannot be found in the prior art, then a rationale must be provided that is reasoned from knowledge generally available to one of ordinary skill in the art, based on established scientific principles, or based on legal precedent established by prior case law. See M.P.E.P. 2144. At least a convincing line of reasoning must be presented to support the rejection. Ex Parte Clapp, 227 U.S.P.Q. 972 (Bd. Pat. App. & Inter. 1985). It is respectfully submitted that the Final Office Action has not provided a convincing line of reasoning for making the proposed modification. The mere blanket assertion that "Hankammer teaches the advantages of having the vanes to guide the water to uniformly penetrate the screen over its entire cross-section, which affords a uniform distribution of water instead of it falling vertically through the filtering material ... [o]ne of ordinary skill in the art would be motivated to use this teaching of the Kanno reference to obtain the distribution as required in Kanno reference ..." hardly amounts to a convincing line of reasoning. As such, the present rejection is apparently based on nothing more that improper hindsight, which cannot support an obviousness rejection.

Furthermore, a person of ordinary skill in the art would not combine Kanno et al. with Hankammer because such a combination would render Kanno et al. inoperable. M.P.E.P. § 2145 provides that a "claimed combination cannot change the principle of

operation of the primary reference or render the reference inoperable for its intended purpose." The principle of operation of Kanno et al. is "to provide a dialyzer having hollow fibers, wherein a ***dialysate*** can come into as uniform a contact as possible with all the hollow fibers, thereby to elevate dialysis efficiency." Col. 1, lines 62 to 65, emphasis added. The Kanno et al. reference goes on to explain that this is accomplished by "a ***dialysate deflection or dispersion member*** disposed in the vicinity of at least the ***dialysate inlet and outlet ports*** for dispersing a flow of ***dialysate***." Col. 2, lines 18 to 21, emphasis added. This is shown in Figure 3 of Kanno et al. where support member 27 acts to disperse the *dialysate*. In order to achieve this function Kanno et al. requires a blood inlet flow in an axial direction through an axial inlet pipe. See, e.g., Figures 2 and 3; col. 4, lines 3 to 17. As described above, the apparatus shown in Hankammer requires a flow from the sides and does not have an axial inlet. Thus, the device disclosed in Hankammer would not permit an axial inlet flow of blood and would therefore change the principle of operation of Kanno et al. and render it inoperable for its intended purpose.

The Final Office Action argues that the "use of the vanes taught by the Hankammer reference in the Kanno inlet would not make the Kanno reference inoperable ... [c]ombining the references does not mean that they are being bodily incorporated in to each other. Final Office Action, page 10. The Final Office Action appears to be relying on an erroneous interpretation of In re Keller, 642 F.2d 413, 425 (C.C.P.A. 1981) and M.P.E.P. § 2145. In re Keller, as cited in the M.P.E.P. § 2145, provides that "'[t]he test for obviousness is not whether the features of the secondary reference may be bodily incorporated into the structure of the primary reference... [r]ather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.'" 642 F.2d at 425. However, in contradiction to the Final Office Action, M.P.E.P. § 2145 goes on to state "*the claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose.*" Emphasis added. As set forth above, the asserted combination of Kanno et al. and Hankammer does just this. A person of ordinary skill in the art would not have been motivated to use the arrangement of Hankammer in the device of Kanno et al. because the device of Kanno et al. is not suitable to permit fluid flow in the manner in which fluid flows in Hankammer, i.e., through the sides of the device.

In light of the foregoing, Applicant respectfully maintains that a person of ordinary skill in the art would not have been motivated to use the arrangement of Hankammer in the device of Kanno et al. Accordingly, it is respectfully submitted that the Final Office Action has failed to establish a prima facie case of obviousness under 35 U.S.C. § 103(a).

For at least the foregoing reasons, it is respectfully submitted that the combination of Kanno et al. and Hankammer does not render unpatentable claims 55 to 64, 67, 69 to 78, 81, 83 to 92, 94, 95, 97 to 105, 107, 108, 110 to 117, 119 and 121 to 126.

C. The rejection of claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117, 119 to 127 and 131 to 133 under 35 U.S.C. §103(a) as unpatentable over Heilmann `883 should be reversed.

Claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117, 119 to 127 and 131 to 133 stand finally rejected under 35 U.S.C. §103(a) as unpatentable over Heilmann `883. It is respectfully submitted that Heilmann `883 does not render obvious the these claims for at least the following reasons.

Independent claims 55, 68, 69, 82, 83, 96, 97, 109, 110, 120, 121 and 124 recite, inter alia, the feature that the members and the end cap are a single structural component and that the members extend away from an upper interior surface of the end cap in a generally axial direction.

Heilmann `883 discloses a flat perforated disk 46 interposed between inlet 28 of end cap 30 and filter element 20 of housing 12. See Figures 1 to 3. Flat disk 46 has flow-directing elements 50 located on a surface facing inlet 28. Id. Flat disk 46 is spaced apart from the upper interior surface of the interior chamber of the end cap. Id. Flat disk 46 is not formed as part of the end cap. Instead, flat disk 46 is a separate structural component that is *installed* in the end cap and rests on an annular notch 74 located on the side surface of the end cap thereby by forming two flow chambers 42 and 44. Page 9, paragraph 3; Figure 3. Flat disk 46 and its flow-directing elements 50 do not extend away from the upper interior surface of the end cap but instead extend away from the surface of flat disk 46. Page 10, paragraph 1.

Heilmann `883 does not render obvious independent claims 55, 68, 69, 82, 83, 96, 97, 109, 110, 120, 121 and 124 for at least the reason that Heilmann `883 fails to disclose, or even suggest that the members and the end cap are a single structural component. Additionally, Heilmann `883 fails to disclose, or even suggest, that the members extend away from an upper interior surface of the end cap in a generally axial direction.

The Final Office Action admits that "[t]he reference [Heilmann `883] differs from the claims in the recitation of the curved member and the end cap being a single structural component." Final Office Action, page 6. However, the Final Office Action contends that such a one piece construction is not a patentable limitation. Id. Citing In re Larson, the Final Office Action argues that "'the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice.'" Final Office Action, page 6 citing In re Larson, 340 F.2d 965, 968 (CCPA 1965). In In re Larson, the Court found that omission of additional framework and axle which served to increase the cargo carrying capacity of prior art mobile fluid carrying unit would have been

obvious *if this feature was not desired.* In re Larson, 340 F.2d at 968. As set forth in M.P.E.P. § 2144.04, wherein In re Larson is cited, the omission of an element and its function is obvious *if the function of the element is not desired.* However, M.P.E.P. § 2144.04 goes on to state:

> ***the omission of an element and retention of its function is an indicia of unobviousness.*** *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966) (Claims at issue were directed to a printed sheet having a thin layer of erasable metal bonded directly to the sheet wherein said thin layer obscured the original print until removal by erasure. The prior art disclosed a similar printed sheet which further comprised an intermediate transparent and erasure-proof protecting layer which prevented erasure of the printing when the top layer was erased. The claims were found unobvious over the prior art because ... although the transparent layer of the prior art was eliminated, the function of the transparent layer was retained since appellant's metal layer could be erased without erasing the printed indicia.).

M.P.E.P. § 2144.04, emphasis added. The *claims of the present invention eliminate the element of flat disk 46,* as disclosed in Heilmann `883, by the members and end cap being a single structural unit. However, *the function of flat disk 46—distributing a fluid—has been retained* by the members and end cap acting as a single structural unit. See, e.g., Figures 8, 11 and 12 and the Specification, page 4, line 27 to page 5, line 7 and page 10, lines 11 to 17, wherein the members and the end cap are shown as a single structural unit and are described as distributing a fluid. Accordingly, as set forth in M.P.E.P. § 2144.04, and In re Edge, the omission of flat disk 46 while retaining the function is indicia of unobviousness, *not* obviousness.

The Final Office Action also argues "[w]ith regard to the curved members being extending in the first direction away from an interior surface, the vanes extend form an interior surfaces (46 and 54) of the end cap in the axial direction." Final Office Action, page 6. The Final Office Action attempts to support the contention that members 50 extend from surface 54 by reasoning that "elements (50) are also described as serving as spacers that prevent the plate (46) from resting against the end cap, which means the elements (50) can be in physical contact with the surface (54) of the end cap as well, which would make the elements (50) as extending also from the surface (54)." Id. Heilmann `883, however, discloses flat disk 46 spaced apart from the interior surface of the interior chamber of the end cap. See Figures 1 and 3. Moreover, contrary to the reasoning argued in the Final Office

Action, the actual language recited in Heilmann `883 provides that "the flow-directing elements (50) may serve as spacers to the inside surface (54) of the end cap and, thus, prevent the plate (54) from resting against the end cap (24) ... [m]oreover, the bottom side (56) of the plate (46), which faces the poured layer (22), also exhibits spacer elements (58) which prevent a loosely inserted plate (46) from closing off the surface (36) of the poured layer (22) ...." Page 14, paragraphs 3 and 4; see also page 9, paragraph 4 to page 10 paragraph 1 ("a plate is also conceivable that is loosely arranged within the end cap ... in such a case, it is of advantage that ... axial spacer elements are also provided both above and below the plate level, so that a first and second flow chamber is safely formed ... [o]therwise, the danger exists that one of these spaces would be compressed by the plate and would, thus, no longer be available for the passage of the flow.") Thus, the use of flow directing elements as "spacers" for "a loosely inserted plate" is not a disclosure of members extending away from an upper interior surface of an end cap. According to Heilmann `883, the use of "spacer elements" is simply to prevent a "loosely" fitting plate from blocking a passage of flow. The fact that the plate is loosely inserted means that there will necessarily be a gap between the upper interior surface of the end cap described in Heilmann `883 because flow-directing elements 50 do not extend from an interior surface of the end cap, but rather extend from the flat disk 46. Page 10, paragraph 1; Figures 1 and 3.

For at least the foregoing the reasons, the features of the feature that the members and the end cap are a single structural component and that the members extend away from an upper interior surface of the end cap in a generally axial direction, as recited in independent claims 55, 68, 69, 82, 83, 96, 97, 109, 110, 120, 121 and 124 are not disclosed or suggested by Heilmann `883.

As for claims 56 to 63, 67, 69 to 78, 81, 84 to 92, 94, 95, 98 to 105, 107, 108, 111 to 117, 119, 122, 123, 125 to 127 and 131 to 133, each of which ultimately depends from and include all of the limitations of a respective one of independent claims 55, 68, 69, 82, 83, 96, 97, 109, 110, 120, 121 and 124, it is respectfully submitted that Heilmann `883 does not render unpatentable these dependent claims for at least the same reasons given above in support of the patentability of claims 55, 68, 69, 82, 83, 96, 97, 109, 110, 120, 121 and 124.

For at least the foregoing reasons, it is respectfully submitted that Heilmann `883 does not render unpatentable claims 55 to 64, 67 to 78, 81 to 92, 94 to 105, 107 to 117, 119 to 127 and 131 to 133.

8. CLAIMS APPENDIX

An appendix containing a copy of the claims involved in the present appeal is attached hereto.

9. EVIDENCE APPENDIX

No evidence has been submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132. No other evidence has been entered by the Examiner or relied upon by Appellants in the appeal. An "Evidence Appendix" is nevertheless attached hereto.

10. RELATED PROCEEDINGS APPENDIX

As indicated above in Section II, "[t]here are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellants or the assignee, Fresenius Medical Care Deutschland GMBH, 'which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.'" As such, there are no "decisions rendered by a court or the Board in any proceeding identified pursuant to [37 C.F.R. § 41.37(c)(1)(ii)]" to be submitted. A "Related Proceedings Appendix" is nevertheless attached hereto.

Respectfully submitted,

Dated: Nov. 10, 2006

By: _____

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Claims Appendix

55. An end cap for a filter device comprising:

a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap, a portion of the channel adjacent to the interior chamber defining a fluid flow path in a first generally axial direction; and

at least one curved member wherein the at least one curved member and the end cap are a single structural component, the at least one curved member extending away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first generally axial direction and located within the interior chamber of the end cap defining, for a fluid exiting the channel and flowing into the interior chamber of the end cap, a fluid flow path in a second direction different from the first direction.

56. The end cap of claim 55, wherein the filter device is a dialyzer.

57. The end cap of claim 56, wherein the end cap is attachable to a casing of the dialyzer.

58. The end cap of claim 55, wherein the channel is a blood inlet channel.

59. The end cap of claim 56, wherein the first direction is a direction that is non-radial relative to a direction defined by a hollow fiber bundle positionable in an interior chamber of the dialyzer.

60. The end cap of claim 59, wherein the first direction is a direction that is axial relative to the direction defined by a hollow fiber bundle positionable in an interior chamber of the dialyzer.

61. The end cap of claim 56, wherein the second direction is a direction that is radial relative to a direction defined by a hollow fiber bundle positionable in an interior chamber of the dialyzer.

62. The end cap of claim 55, wherein the at least one member is arranged circumferentially around the channel.

63. The end cap of claim 55, wherein the at least one member extends towards a perimeter of the interior chamber of the end cap.

64. The end cap of claim 55, wherein the at least one member is arranged such that the second direction of the fluid flow path defines an essentially radially symmetrical pattern.

67. The end cap of claim 55, wherein the end cap includes at least two members, respective portions of the members being spaced equidistantly relative to each other.

68. An end cap for a filter device comprising:

a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap, a portion of the channel adjacent to the interior chamber defining a fluid flow path in a first direction; and

at least one member wherein the at least one member and the end cap are a single structural component, the at least one member located within the interior chamber of the end cap and extending away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first direction, the at least one member defining, for a fluid exiting the channel and flowing into the interior chamber of the end cap, a fluid flow path in a second direction different from the first direction, wherein the end cap includes at least two members, respective portions of the members being spaced equidistantly relative to each other, and wherein the distance between respective portions of adjacent members decreases in the second direction of flow.

69. A filter device comprising:

a casing for housing a filter element;

an end cap attachable to the casing, the end cap including a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap, a portion of the channel adjacent to the interior chamber defining a fluid flow path in a first generally axial direction, and at least one curved member wherein the at least one curved member and the end cap are a single structural component, the at least one curved member extending away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first generally axial direction and located within the interior chamber of the end cap defining, for a fluid exiting the channel and flowing into the interior chamber of the end cap, a fluid flow path in a second direction different from the first direction.

70. The filter device of claim 69, wherein the filter device is a dialyzer.

71. The filter device of claim 69, wherein the channel is a blood inlet channel.

72. The filter device of claim 70, wherein the filter element is a hollow fiber bundle.

73. The filter device of claim 72, wherein the first direction is a direction that is non-radial relative to a direction defined by the hollow fiber bundle when the hollow fiber bundle is located in an interior chamber of the dialyzer.

74. The filter device of claim 72, wherein the first direction is a direction that is axial relative to the direction defined by the hollow fiber bundle when the hollow fiber bundle is located in an interior chamber of the dialyzer.

75. The filter device of claim 72, wherein the second direction is a direction that is radial relative to a direction defined by the hollow fiber bundle when the hollow fiber bundle is located in an interior chamber of the dialyzer.

76. The filter device of claim 69, wherein the at least one member is arranged circumferentially around the channel.

77. The filter device of claim 69, wherein the at least one member extends towards a perimeter of the interior chamber of the end cap.

78. The filter device of claim 69, wherein the at least one member is arranged such that the second direction of the fluid flow path defines an essentially radially symmetrical pattern.

81. The filter device of claim 69, wherein the end cap includes at least two members, respective portions of the members being spaced equidistantly relative to each other.

82. A filter device comprising:

a casing for housing a filter element;

an end cap attachable to the casing, the end cap including a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap, a portion of the channel adjacent to the interior chamber defining a fluid flow path in a first direction, and at least one member wherein the at least one member and the end cap are a single structural component, the at least one member located within the interior chamber of the end cap and extending away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first direction, the at least one member defining, for a fluid exiting the channel and flowing into the interior chamber of the end cap, a fluid flow path in a second direction different from the first direction, wherein the end cap includes at least two members, respective portions of the members being spaced equidistantly relative to each other, and wherein the distance between respective portions of adjacent members decreases in the second direction of flow.

83. An end cap for a filter device comprising:

a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap; and

at least one member wherein the at least one member and the end cap are a single structural component, the at least one member extending away from an upper interior surface

of the end cap that is adjacent to the channel in a generally axial direction and located within the interior chamber of the end cap, the at least one member configured to impart a circular motion to fluid exiting the channel and flowing into the interior chamber of the end cap.

84. The end cap of claim 83, wherein the filter device is a dialyzer.

85. The end cap of claim 84, wherein the end cap is attachable to a casing of the dialyzer.

86. The end cap of claim 83, wherein the channel is a blood inlet channel.

87. The end cap of claim 84. wherein a portion of the channel adjacent to the interior chamber defines a fluid flow path in a first direction.

88. The end cap of claim 87, wherein the first direction is a direction that is non-radial relative to a direction defined by a hollow fiber bundle positionable in an interior chamber of the dialyzer.

89. The end cap of claim 87, wherein the first direction is a direction that is axial relative to a direction defined by a hollow fiber bundle positionable in an interior chamber of the dialyzer.

90. The end cap of claim 83, wherein the at least one member is arranged circumferentially around the channel.

91. The end cap of claim 83, wherein the at least one member extends towards a perimeter of the interior chamber of the end cap.

92. The end cap of claim 83, wherein the at least one member is arranged such that the second direction of the fluid flow path defines an essentially radially symmetrical pattern.

94. The end cap of claim 83, wherein the at least one member is curved.

95. The end cap of claim 83, wherein the end cap includes at least two members, respective portions of the members being spaced equidistantly relative to each other.

96. An end cap for a filter device comprising:

a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap in a first direction; and

at least one member wherein the at least one member and the end cap are a single structural component, the at least one member located within the interior chamber of the end cap and extending away from an upper interior surface of the end cap that is adjacent to the

channel in a direction that is the same as the first direction, the at least one member configured to impart a circular motion to fluid exiting the channel and flowing into the interior chamber of the end cap, wherein the end cap includes at least two members, respective portions of the members being spaced equidistantly relative to each other, and wherein the distance between respective portions of adjacent members decreases in the second direction of flow.

97. A filter device comprising:

a casing for housing a filter element;

an end cap attachable to the casing, the end cap including a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap, the channel defining a fluid flow path in a first generally axial direction, and at least one member wherein the at least one member and the end cap are a single structural component, the at least one member extending away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first generally axial direction and located within the interior chamber of the end cap, the at least one member configured to impart a circular motion to fluid exiting the channel and flowing into the interior chamber of the end cap.

98. The filter device of claim 97, wherein the filter device is a dialyzer.

99. The filter device of claim 97, wherein the channel is an inlet channel.

100. The filter device of claim 97, wherein the filter element is a hollow fiber bundle.

101. The filter device of claim 97, wherein a portion of the channel adjacent to the interior chamber defines a fluid flow path in a first direction.

102. The filter device of claim 101, wherein the first direction is a direction that is non-radial relative to a direction defined by a hollow fiber bundle positionable in an interior chamber of the dialyzer.

103. The filter device of claim 98, wherein the first direction is a direction that is axial relative to a direction defined by the hollow fiber bundle when the hollow fiber bundle is located in an interior chamber of the dialyzer.

104. The filter device of claim 97, wherein the at least one member is arranged circumferentially around the channel.

105. The filter device of claim 97, wherein the at least one member extends towards a perimeter of the interior chamber of the end cap.

107. The filter device of claim 97, wherein the at least one member is curved.

108. The filter device of claim 97, wherein the end cap includes at least two members, respective portions of the members being spaced equidistantly relative to each other.

109. A filter device comprising:

a casing for housing a filter element;

an end cap attachable to the casing, the end cap including a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap, the channel defining a fluid flow path in a first direction, and at least one member wherein the at least one member and the end cap are a single structural component, the at least one member located within the interior chamber of the end cap and extending away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first direction, the at least one member configured to impart a circular motion to fluid exiting the channel and flowing into the interior chamber of the end cap, wherein the end cap includes at least two members, respective portions of the members being spaced equidistantly relative to each other, and wherein the distance between respective portions of adjacent members decreases in the second direction of flow.

110. A hemodialyzer device comprising:

a casing forming a housing, the casing having a blood outlet channel;

a hollow fiber bundle stored within the casing;

an end cap attachable to the casing, the end cap including a blood inlet channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap, the channel defining a fluid flow path in a first generally axial direction, and a plurality of curved members wherein the plurality of curved members and the end cap are a single structural component, the plurality of curved members extending away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first generally axial direction and located within the interior chamber of the end cap, the at least one member defining, for a fluid exiting the channel and flowing into the interior chamber of the end cap, a fluid flow path in a second direction different from the first direction.

111. The hemodialyzer device of claim 110, wherein a portion of the channel adjacent to the interior chamber defines a fluid flow path in a first direction.

112. The hemodialyzer device of claim 111, wherein the first direction is a direction that is non-radial relative to the casing.

113. The hemodialyzer device of claim 112, wherein the first direction is a direction that is axial relative to the casing.

114. The hemodialyzer device of claim 110, wherein the second direction is a direction that is radial relative to the casing.

115. The hemodialyzer device of claim 110, wherein the plurality of members are arranged circumferentially around the channel.

116. The hemodialyzer device of claim 110, wherein the plurality of members extend towards a perimeter of the interior chamber of the end cap.

117. The hemodialyzer device of claim 110, wherein the plurality of members are arranged such that the second direction of the fluid flow path defines an essentially radially symmetrical pattern.

119. The hemodialyzer device of claim 110, wherein respective portions of each one of the plurality of members are spaced equidistantly relative to each other.

120. A hemodialyzer device comprising:

a casing forming a housing, the casing having a blood outlet channel;

a hollow fiber bundle stored within the casing;

an end cap attachable to the casing, the end cap including a blood inlet channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap, the channel defining a fluid flow path in a first direction, and a plurality of curved members wherein the plurality of curved members and the end cap are a single structural component, the plurality of curved members located within the interior chamber of the end cap and extending away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first direction, the at least one member defining, for a fluid exiting the channel and flowing into the interior chamber of the end cap, a fluid flow path in a second direction different from the first direction, wherein respective portions of each one of the plurality of members are spaced equidistantly relative to each other, and wherein the distance between respective portions of adjacent members decreases in the second direction of flow.

121. A method for filtering a fluid, comprising the steps of:

passing the fluid through a filter device, the filter device including a casing for housing a filter element and an end cap attachable to the casing, the end cap including a channel providing fluid communication from an exterior of the end cap to an interior chamber of the end cap, a portion of the channel adjacent to the interior chamber defining a fluid flow path in a first generally axial direction, and at least one curved member wherein the at least

one curved member and the end cap are a single structural component, the at least one curved member extending away from an upper interior surface of the end cap that is adjacent to the channel in a direction that is the same as the first generally axial direction and located within the interior chamber of the end cap defining, for a fluid exiting the channel and flowing into the interior chamber of the end cap, a fluid flow path in a second direction different from the first direction.

122. The method of claim 121, wherein the step of passing the fluid through the filter device involves passing blood through the filter device.

123. The method of claim 122, wherein the step of passing blood through the filter device involves passing blood through a dialyzer.

124. A method for filtering a fluid, comprising the steps of:

passing the fluid through a filter device, the filter device including a casing for housing a filter element and an end cap attachable to the casing, the end cap including a channel providing fluid communication in a generally axial direction from an exterior of the end cap to an interior chamber of the end cap, and at least one member defined by an interior surface of, and located within, the interior chamber of the end cap, the interior surface being adjacent to the channel, the at least one member forming part of the end cap wherein the at least one member and the end cap are a single structural component, the at least one member configured to impart a circular motion to fluid exiting the channel and flowing into the interior chamber of the end cap.

125. The method of claim 124, wherein the step of passing the fluid through the filter device involves passing blood through the filter device.

126. The method of claim 125, wherein the step of passing blood through the filter device involves passing blood through a dialyzer.

127. The end cap of claim 83, wherein a portion of the channel adjacent to the interior chamber is curved.

128. The end cap of claim 127, wherein the cross-sectional area of the curved channel decreases in the direction of fluid flow.

129. The end cap of claim 83, wherein a portion of the channel adjacent to the interior chamber forms a circle.

130. The end cap of claim 83, wherein a portion of the channel adjacent to the interior chamber forms a semicircle.

131. The end cap of claim 83, further comprising an inlet extending radially from the channel.

132. The end cap of claim 83, further comprising an inlet in fluid connection with the channel and extending in a general radial direction.

133. The hemodialyzer device of claim 110, wherein the end cap further comprises a connection for a flow space formed by an interior of the casing and an exterior of hollow fibers in the hollow fiber bundle, the connection providing fluid communication between the exterior of the end cap to the flow space and extending in a generally radial direction.

Evidence Appendix

No evidence has been submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132. No other evidence has been entered by the Examiner or relied upon by Appellants in the appeal.

Related Proceedings Appendix

As indicated above in Section II, "[t]here are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellants or the assignee, Fresenius Medical Care Deutschland GMBH, 'which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.'" As such, there are no "decisions rendered by a court or the Board in any proceeding identified pursuant to [37 C.F.R. § 41.37(c)(1)(ii)]" to be submitted.